





INTERNATIONAL FORMULA COUNCIL

Formerly the Enteral Nutrition Council and Infant Formula Council

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ATTACHMENT E

Via E-mail and Federal Express

July 7, 2003

Dr. Christine Taylor, HFS-800
Food and Drug Administration
CFSAN, CPK1/4C096
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Taylor:

The infant formula industry* continues to evaluate the development of additional liquid formulas for use with extremely low birth weight infants, especially in the NICU, as discussed at the FDA's Food Advisory Committee, Subcommittee on Contaminants and Natural Toxicants, in March 2003. At present there remain important medical considerations relating to premature infant feeding that we would like to be sure FDA is considering.

There is increasing recognition among neonatologists concerning the incidence of poor growth among extremely low birth weight infants (<1000 g BW). Although 10% to 15% of these infants have body weights below the 10th percentile at birth, weights of these infants fall below the 10th percentile in 90% to 100% of these infants by the time they are discharged from the hospital. Causes of poor growth are multifactorial and related to the gastrointestinal and metabolic immaturity and the medical morbidity of prematurity. In part, the goal of neonatologists often must balance a need to restrict fluid intake with delivering nutrition that is rich in protein and calcium as well as sodium and potassium, singly or in combination, depending upon the infant's clinical circumstances. In addition, the mothers of these infants may be providing expressed breast milk, which is recognized to be nutritionally insufficient for preterm infants, and varies in nutrient content. The availability of various powders, including those that provide protein, offer neonatologists flexibility to provide individualized nutrition that simultaneously 1) maintains fluid restriction, 2) delivers specific nutrients, and 3) improves growth. A decision to remove powders from the NICU may place neonatologists in a position of having to accept malnutrition among most of these infants in an attempt to avoid a low possible (albeit serious) risk of infection.

We would welcome the opportunity to discuss this further with you at our July 8th meeting or elsewhere if you would like.

Sincerely,

Robert C. Gelardi

Robert C. Gelardi
President

Mardi K. Mountford

Mardi K. Mountford
Executive Director

* Note: United States infant formula manufacturers are Bristol-Myers Squibb, Mead Johnson Nutritionals; Nestlé USA, Nutrition Division; Abbott Laboratories, Ross Products Division; Solus Products; and Wyeth Nutrition.